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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/241,636 02/02/99 HEATH E 5253

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HM12/0705

EXAMINER

GOLDBERG, J

ART UNIT

PAPER NUMBER

1655

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/241,636

Applicant(s)

HEATH ET AL.

Examiner

Jeanine A Enewold Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after non-final rejection. Since this application is not eligible for continued examination under 37 CFR 1.114, the submission filed on May 22, 2001 has been treated as an amendment under 37 CFR 1.111.
2. Currently, claims 1-10, 12-62 are pending. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow.
3. Any objections and rejections not reiterated below are hereby withdrawn.
4. This action is made FINAL.
5. This action contains new grounds of rejection necessitated by amendment.

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-3, 5-6, 11-21, 23-30, 32-33, 37, 39, 41, 45-51, 53-56, 58, 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom et al (5,234,809) in view of Shieh (US Pat. 6,054,039, April 2000).

Boom teaches methods of characterizing DNA. Boom discloses a process which involved contacting the biological material that contains DNA with a solid support that had been treated with a lysing reagent (i.e. a chaotropic substance), treating the biological material with a purifying reagent, and purifying the DNA (col. 4, lines 3-59). The chaotropic substance (lysing reagent) is contacted with silica particles (solid support). The biological material is then treated with purifying reagents, and the remainder of the biological matter is purified (washing buffer, alcohol washing solution and acetone. Additionally, the process described by Boom produces DNA which can be further used to "demonstrate NA sequences by means of an amplification method such as the PCR method...." (col.4, lines 48-50)(limitations of claims 24-27 and 45-46). Since Boom teaches that the Gus SCN (i.e. the lysis reagent) is added to the solid support (i.e. the silica beads) prior to addition of biological material, Boom is inherently teaching a solid support to which a lysing reagent is "bound." The term "bound" is being broadly interpreted to mean loosely and transiently in contact with the solid support. As described in Boom, the DNA may be eluted from the solid support by means of an eluting reagent (col.4, line 33). Boom teaches an eluting reagent can be TE buffer, aqua bidest or PCR buffer. Boom further teaches the process where in the solid support is contained in a single vessel (col.4, lines 34-36) (limitations of claims 3 and 28). Boom demonstrates the use of isolating nucleic acids from a nucleic acid-containing biological material (col. 1, lines 10-20). The biological material stated includes tissues, cell cultures, blood, urine, and saliva (body fluids)(limitations of claims 5-6, 29-30). The nucleic acid was taught to be examined by gel electrophoresis (col. 10, lines 13-24)

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(limitations of claims 12-17, 19, 21, 47-49). This method may be used for characterizing the biological material and monitoring impurities. Yields were also taught in example A1 (col. 12, lines 46-48)(limitations of claim 18). Eluted DNA was treated with a restriction enzyme, electrophoresed and visualized (col 12 65-68) (limitations of claims 21 and 50). Boom also teaches hybridization analysis of the isolated nucleic acids (col. 9, lines 19-21)(limitations of claims 23 and 53). Boom teaches a method which can "provide a process with which nucleic acid can be isolated immediately..." (col. 1, lines 64-67) (limitation of claim 32). Boom teaches lysis buffers containing Tris (buffer), aqua bidest, GuSCN, and EDTA (col 6, lines 39-68).

Boom does not explicitly teach using a solid support in which the lysing reagent is bound, and unbound lysing reagent is removed prior to the contacting of the biological treatment.

However, Shieh teaches a method for characterizing DNA by contacting a biological material that contains DNA with a solid support pre-treated with a lysing reagent, treating the biological material with a DNA purifying reagent, purifying the DNA from the remainder of the biological material and analyzing the DNA. Specifically, Shieh teaches the modification of a membrane strip to produce lysis of red blood cells that contacts it (col. 6, lines 17-20). Shieh teaches that membranes such as polymer treated glass fibers, polyamides, cellulose, polyesters may be used (col. 10, lines 42-57)(limitations of Claims 33). Shieh teaches preparing a lysing component by treating the membranes with a lysing agent (col. 10, lines 65-67). Shieh teaches that lysing agents included Mega 8, Triton X, lauryl sulfate sals, TEA sals, sodium salt,

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among numerous others (col. 11, lines 1-10)(limitations of Claims 61-62). Furthermore, Shieh teaches that the lysing agent may be coated onto the membrane by any method used in the art for coating solutions onto films such as dip coating an aqueous solution or dispersion of the lysing solution onto the membrane and allowing to dry (col. 11, lines 10-20). As provided in Example 1D, a cell lysing membrane was prepared (col. 12, lines 8-18). Furthermore, Shieh teaches that "this component caused lysis of whole blood when it passed across the membrane (col. 14, lines 31-33). Shieh teaches that the method and sensor may be used "on the spot: at home, in a physicians office or in a hospital room". Shieh also teaches the sensor is low cost and disposable (col. 15, lines 55-60).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Boom, which characterizes DNA using a solid support, lysing reagent and a biological material with the method and pre-treated membrane of Shieh. Shieh teaches that biological samples may be lysed using a pre-treated membrane such that lysis is caused when a sample is passed across the membrane. The ordinary artisan would have been motivated to have produced a solid support which was pre-treated with a lysing reagent, as taught by Shieh, for the expected benefit taught by Shieh as low cost and disposability. The ordinary artisan would also have been motivated to have prepared the pre-treated lysing membranes, of Shieh, for use in the method, of Boom, for the expected benefit of convenience. Moreover, the skilled artisan would have had a reasonable expectation of success for analyzing DNA from a solid support that was pretreated with a lysing

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reagent since Boom teaches a method in which all three components, a lysing reagent, solid support and nucleic acid sample, were contacted with successful results. Thus, the skilled artisan would have combined the teachings of Boom with the teachings of Shieh.

Response to Arguments

The response traverses the rejection. The response asserts that "Shieh merely teaches the separation of red blood cells from whole blood and their lysis thereafter....The method of the present invention does not preferentially filter out blood components like the method disclosed in Shieh". This argument has been reviewed but is not convincing because the teachings of Shieh illustrate that a lysing matrix may be formed by drying the lysing solution onto the membrane prior to contact with a biological material. The combination of this teaching that drying the lysing solution onto the membrane prior to contact with a biological material and the teachings of Boom that DNA may be characterized by lysing a biological material, using a purifying reagent, purifying, and analyzing the DNA. The art clearly teaches a lysing reagent bound to a solid support and removing any unbound lysing reagent prior to the contact with a biological material. Thus, as provided above, "The ordinary artisan would have been motivated to have produced a solid support which was pre-treated with a lysing reagent, as taught by Sheih, for the expected benefit taught by Shieh as low cost and disposability. The ordinary artisan would also have been motivated to have prepared the pre-treated lysing membranes, of Shieh, for use in the method, of Boom, for the expected benefit of convenience. Moreover, the skilled artisan would have had a

reasonable expectation of success for analyzing DNA from a solid support that was pretreated with a lysing reagent since Boom teaches a method in which all three components, a lysing reagent, solid support and nucleic acid sample, were contacted with successful results." Thus for the reasons above and those already of record, the rejection is maintained.

7. Claims 1-20, 24-33, 37-41, 44-49, 54-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deggerdal (WO 96/18731) in view of Shieh (US Pat. 6,054,039, April 2000).

Deggerdal teaches methods of characterizing DNA. Deggerdal discloses a "method of isolating nucleic acid from a sample, said method comprising contacting said sample with a detergent and a solid support, whereby soluble nucleic acid in said sample is bound to the support, and separating said support with bound nucleic acid from the sample" (pg 5, para 2). Deggerdal teaches that the "nucleic acid-containing sample may be contacted with the detergent and solid phase which may be added to the sample prior to, simultaneously with, or subsequently to the detergent (which functions in the method to lyse)"(pg 7, para 3, lines 22-29). Deggerdal is inherently teaching a solid support to which a lysing reagent is "bound." The term "bound" is being broadly interpreted to mean loosely and transiently in contact with the solid support. The solid support was contained in a vessel (pg 26, line 18). Deggerdal teaches isolation of nucleic acids and the elution of the nucleic acid by heating to 65 C for 5-10 minutes (pg 12, para 3, line 3)(limitations of claims 4 and 44). The samples may be of "any material containing nucleic acid" (pg 6, para 1, line 1-3)(limitations of claims 5-7 and 29-31).

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Deggerdal teaches a method of DNA isolation from cultured cells which indicates the number of cells used as starting material (pg 33, line 1) (limitations of claims 8-10). The purified DNA was then analyzed by PCR and visualized on agarose gel electrophoresis (pg 20, lines 29-32). Detection of extra bands indicated contamination (pg 17, lines 26-27). The solid support was taught to be made of "glass, silica, latex or a polymeric material" (pg 9, para 3)(limitations of claim 33). Deggerdal teaches an example where cells were lysed using DNA DIRECT Dynabeads and the lysate from each sample was further characterized (pg 35, lines 6-35)(limitations of claim 11). Deggerdal teaches the lysing reagent as a detergent. This detergent may be supplied in simple aqueous solution (pg 8, line 7). Further any suitable buffer (Tris) is taught. The reagent may also include components such as enzymes, chelating agents and reducing agents (pg 8, lines 7-23) (limitations of claims 37-41).

Deggerdal does not explicitly teach using a solid support in which the lysing reagent is bound, and unbound lysing reagent is removed prior to the contacting of the biological treatment.

However, Shieh teaches a method for characterizing DNA by contacting a biological material that contains DNA with a solid support pre-treated with a lysing reagent, treating the biological material with a DNA purifying reagent, purifying the DNA from the remainder of the biological material and analyzing the DNA. Specifically, Shieh teaches the modification of a membrane strip to produce lysis of red blood cells that contacts it (col. 6, lines 17-20). Shieh teaches that membranes such as polymer treated glass fibers, polyamides, cellulose, polyesters may be used (col. 10, lines 42-

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57)(limitations of Claims ***). Shieh teaches preparing a lysing component by treating the membranes with a lysing agent (col. 10, lines 65-67). Shieh teaches that lysing agents included Mega 8, Triton X, lauryl sulfate sals, TEA sals, sodium salt, among numerous others (col. 11, lines 1-10)(limitations of Claims ***). Furthermore, Shieh teaches that the lysing agent may be coated onto the membrane by any method used in the art for coating solutions onto fils such as dip coating an aqueous solution or disperson of the lysing solution onto the membrane and allowing to dry (col. 11, lines 10-20). As provided in Example 1D, a cell lysing membrane was prepared (col. 12, lines 8-18). Furthermore, Shieh teaches that "this component caused lysis of whole blood when it passed across the membrane (col. 14, lines 31-33). Shieh teaches that the method and sensor may be used "on the spot: at home, in a physicians office or in a hospital room". Shieh also teaches the sensor is low cost and disposable (col. 15, lines 55-60).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Deggerdal, which characterizes DNA using a solid support, lysing reagent and a biological material with the method and pre-treated membrane of Shieh. Shieh teaches that biological samples may be lysed using a pre-treated membrane such that lysis is caused when a sample is passed across the membrane. The ordinary artisan would have been motivated to have produced a solid support which was pre-treated with a lysing reagent, as taught by Sheih, for the expected benefit taught by Shieh as low cost and disposibility. The ordinary artisan would also have been motivated to have prepared the pre-treated lysing

membranes, of Shieh, for use in the method, of Deggerdal, for the expected benefit of convenience. Moreover, the skilled artisan would have had a reasonable expectation of success for analyzing DNA from a solid support that was pretreated with a lysing reagent since Deggerdal teaches a method in which all three components, a lysing reagent, solid support and nucleic acid sample, were contacted with successful results. Thus, the skilled artisan would have combined the teachings of Deggerdal with the teachings of Shieh.

Response to Arguments

The response traverses the rejection. The response asserts that "Shieh merely teaches the separation of red blood cells from whole blood and their lysis thereafter". This argument has been reviewed but is not convincing because the teachings of Shieh illustrate that a lysing matrix may be formed by drying the lysing solution onto the membrane prior to contact with a biological material. The combination of this teaching that drying the lysing solution onto the membrane prior to contact with a biological material and the teachings of Deggerdal that DNA may be characterized by lysing a biological material, using a purifying reagent, purifying, and analyzing the DNA. The art clearly teaches a lysing reagent bound to a solid support and removing any unbound lysing reagent prior to the contact with a biological material. Thus, as provided above, "The ordinary artisan would have been motivated to have produced a solid support which was pre-treated with a lysing reagent, as taught by Sheih, for the expected benefit taught by Shieh as low cost and disposibility. The ordinary artisan would also have been motivated to have prepared the pre-treated lysing membranes, of Shieh, for

use in the method, of Deggerdal, for the expected benefit of convenience. Moreover, the skilled artisan would have had a reasonable expectation of success for analyzing DNA from a solid support that was pretreated with a lysing reagent since Deggerdal teaches a method in which all three components, a lysing reagent, solid support and nucleic acid sample, were contacted with successful results." Thus for the reasons above and those already of record, the rejection is maintained.

8. Claims 38 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom (5,234,809) in view of Shieh (US Pat. 6,054,039, April 2000) as applied to Claims 1-3, 5-6, 11-21, 23-30, 32-33, 37, 39, 41, 45-51, 53-56, 58, 60-62 above, and further in view of in view of Deggerdal (WO 96/18731).

Niether Boom, nor Shieh teaches a lysing reagent which does not contain a buffer.

Deggerdal, however, teaches a lysing reagent as a detergent. This detergent may be supplied in simple aqueous solution (pg 8, line 7). Further any suitable buffer (Tris) is taught. The reagent may also include components such as enzymes, chelating agents and reducing agents (pg 8, lines 7-23) (limitations of claims 37-41).

Therefore, it would have been prima facie obvious to one of ordinary skill at the time of the invention was made to have modified the method of Boom in view of Shieh to include the use of the lysing reagents taught in Deggerdal. The ordinary artisan would have been motivated to use the lysing reagents taught in Deggerdal because the lysing reagents taught in Deggerdal were readily available.

Response to Arguments

The response traverses the rejection. The response asserts the aforementioned discussion detailing the differences between the instant invention and the cited art overcome the rejection cited by the Examiner. This argument has been reviewed but is not convincing because the Shieh teaches a solid support with lysing material dried upon the support to serve as a lysing matrix. Thus for the reasons above and those already of record, the rejection is maintained.

9. Claims 23 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deggerdal (WO 96/18731) in view of Shieh (US Pat. 6,054,039, April 2000) as applied to Claims 1-20, 24-33, 37-41, 44-49, 54-62 above and further in view of Boom (5,234,809).

Neither Deggerdal, nor Shieh specifically teaches conducting a hybridization analysis on the amplified DNA.

However, Boom teaches hybridization analysis of the isolated nucleic acids (col. 9, lines 19-21).

Therefore, it would have been prima facie obvious to one of ordinary skill at the time of the invention was made to have applied the method of Deggerdal in view of Shieh to include the method of hybridization reactions as used in the method of Boom. The ordinary artisan would have been motivated to have conducted hybridization reactions taught in the method of Boom on the isolated DNA obtained from the Deggerdal method to further characterize the DNA sample.

Response to Arguments

The response traverses the rejection. The response asserts the aforementioned discussion detailing the differences between the instant invention and the cited art overcome the rejection cited by the Examiner. This argument has been reviewed but is not convincing because the Shieh teaches a solid support with lysing material dried upon the support to serve as a lysing matrix. Thus for the reasons above and those already of record, the rejection is maintained.

10. Claims 7, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom (5,234,809) in view of Shieh (US Pat. 6,054,039, April 2000) as applied to Claims 1-3, 5-6, 11-21, 23-30, 32-33, 37, 39, 41, 45-51, 53-56, 58, 60-62 above and further in view of Su (5,804,684).

Niether Boom, nor Shieh specifically teaches biological material from the group consisting of environmental samples taken from air, water, sediment and soil.

However, Su teaches a list of samples which includes "any type of biological sample....environmental, nutritional, scientific or industrial significance" (col.8, lines 3-16).

Therefore, it would have been prima facie obvious to one of ordinary skill at the time of the invention was made to have applied the method of Boom in view of Shieh to include the use of environmental samples as the biological starting material as used in the method of Su. The ordinary artisan would have been motivated to have sampled the biological materials from the environment because environmental samples are a well

known source of clinically important DNA containing organisms whose detection is necessary to prevent disease spread, for example.

Response to Arguments

The response traverses the rejection. The response asserts the aforementioned discussion detailing the differences between the instant invention and the cited art overcome the rejection cited by the Examiner. This argument has been reviewed but is not convincing because the Shieh teaches a solid support with lysing material dried upon the support to serve as a lysing matrix. Thus for the reasons above and those already of record, the rejection is maintained.

11. Claims 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom (5, 804,684) in view of Shieh (US Pat. 6,054,039, April 2000) as applied to Claims 1-3, 5-6, 11-21, 23-30, 32-33, 37, 39, 41, 45-51, 53-56, 58, 60-62 above or Deggerdal (WO 96/18731) in view of Shieh (US Pat. 6,054,039, April 2000) as applied to Claims 1-20, 24-33, 37-41, 44-49, 54-62 above and further in view of Su (5,804,684).

Niether Boom in view of Shieh nor Deggerdal in view of Shieh specifically teach the eluting reagent as specified in the claims.

However, Su teaches the elution buffer to be 5 mM Tris HCl, pH 9, and 0.5 mM EDTA (col 10, line 17).

Therefore, it would have been prima facie obvious to one of ordinary skill at the time of the invention was made to have modified the method of Boom in view of Shieh or Deggerdal in view of Shieh to include the use of the elution buffer described in the

method of Su. The ordinary artisan would also have expected that using the elution buffer of Su in the method of Boom or Deggerdal with the elution buffer described in Su would have provided equivalent results.

Response to Arguments

The response does not specifically address this rejection. However it is presumed that the response traverses the rejection. The response asserts the aforementioned discussion detailing the differences between the instant invention and the cited art overcome the rejection cited by the Examiner. This argument has been reviewed but is not convincing because the Shieh teaches a solid support with lysing material dried upon the support to serve as a lysing matrix. Thus for the reasons above and those already of record, the rejection is maintained.

12. Claims 22 and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom (5, 804,684) in view of Shieh (US Pat. 6,054,039, April 2000) as applied to Claims 1-3, 5-6, 11-21, 23-30, 32-33, 37, 39, 41, 45-51, 53-56, 58, 60-62 above or Deggerdal (WO 96/18731) in view of Shieh (US Pat. 6,054,039, April 2000) as applied to Claims 1-20, 24-33, 37-41, 44-49, 54-62 above and further in view of Sambrook (Molecular Cloning).

Niether Boom in view of Shieh nor Deggerdal in view of Shieh specifically teach sequencing the purified DNA.

However, Sambrook teaches the analysis of DNA by nucleic acid sequencing (13.3). Sambrook teaches that the sequences provide the advantage of determining the sequence of nucleotides in a particular DNA molecule.

Therefore, it would have been prima facie obvious to one of ordinary skill at the time of the invention was made to have modified the method of Boom or Deggerdal in view of Shieh to include the sequencing analysis method taught by Sambrook in order to make the claimed invention as a whole. The ordinary artisan would be motivated to have sequenced the purified DNA obtained by the Boom method in order to have achieved the expected advantage of determining the sequence of nucleotides of the isolated DNA.

Response to Arguments

The response does not specifically address this rejection. However it is presumed that the response traverses the rejection. The response asserts the aforementioned discussion detailing the differences between the instant invention and the cited art overcome the rejection cited by the Examiner. This argument has been reviewed but is not convincing because the Shieh teaches a solid support with lysing material dried upon the support to serve as a lysing matrix. Thus for the reasons above and those already of record, the rejection is maintained.

13. Claims 33 and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boom (5, 804,684) in view of Shieh (US Pat. 6,054,039, April 2000) as applied to Claims 1-3, 5-6, 11-21, 23-30, 32-33, 37, 39, 41, 45-51, 53-56, 58, 60-62 above or

Deggerdal (WO 96/18731) in view of Shieh (US Pat. 6,054,039, April 2000) as applied to Claims 1-20, 24-33, 37-41, 44-49, 54-62 above and further in view of Arnold (5,599,667).

Niether Boom, Deggerdal, nor Shieh specifically teach using polyolefin as a solid support wherein polyolefin is hydrophilic and has a charge.

However, Arnold teaches polycationic solid supports that can be used purification of nucleic acids (see abstract). The polycationic support matrix is taught to include inorganic and organic materials which include glasses, polyolefins and polysaccharides (col.8, lines 55-62).

Therefore, it would have been prima facie obvious to one of ordinary skill at the time of the invention was made to have modified the method of Boom or Deggerdal in view of Shieh to include the solid supports of Arnold in order to make the claimed invention as a whole. The ordinary artisan would be motivated to have substituted polyolefins as a solid support in the Boom or Deggerdal method because Arnold taught that polyolefins and glass are both suitable for DNA isolation because they meet the same "principle requirement" of "not unduly adsorbing either contaminants or nucleotide probes (col. 8, lines 61-64). Consequently Arnold shows that the silica of Boom or Deggerdal and the polyolefins of the claims are equivalent.

Response to Arguments

The response traverses the rejection. The response asserts the aforementioned discussion detailing the differences between the instant invention and the cited art overcome the rejection cited by the Examiner. This argument has been reviewed but is

not convincing because the Shieh teaches a solid support with lysing material dried upon the support to serve as a lysing matrix. Thus for the reasons above and those already of record, the rejection is maintained.

14. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boom (5, 804,684) in view of Shieh (US Pat. 6,054,039, April 2000) or Deggerdal (WO 96/18731) in view of Shieh (US Pat. 6,054,039, April 2000) and further in view of Arnold (5,599,6667) as applied to claim 33, 35-36 above, and further in view of Hasebe (5,151,345).

Arnold teaches polycationic solid supports that can be used purification of nucleic acids (see abstract). The polycationic support matrix is taught to include inorganic and organic materials which include glasses, polyolefins and polysaccharides (col.8, lines 55-62).

However, neither Boom or Deggerdal nor Arnold specifically teaches that polyolefin is a mixture of low density polyethylene and polypropylene fibers.

However, Hasebe teaches that "a polyolefin resin is preferred, and low-density polyethylene, high-density polyethylene...or a blend thereof is preferably used"(col 11, lines 32-39).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention was made to combine the methods of Boom or Deggerdal and Arnold as discussed above and use the types of polyolefins taught by

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Hasebe. As Arnold teaches that "polyolefins" may be used in DNA isolation, one of ordinary skill in the art would have been motivated to use a preferred polyolefin resin.

Response to Arguments

The response traverses the rejection. The response asserts the aforementioned discussion detailing the differences between the instant invention and the cited art overcome the rejection cited by the Examiner. This argument has been reviewed but is not convincing because the Shieh teaches a solid support with lysing material dried upon the support to serve as a lysing matrix. Thus for the reasons above and those already of record, the rejection is maintained.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claim 54 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A2) Claim 54 is indefinite because the claims do not recite a positive process step which clearly relates back to the preamble. The preamble states that the method is for characterizing DNA but the final process step is analyzing the DNA. Therefore the claims are unclear as to whether the method is a method of characterizing or analyzing

DNA. Characterizing the DNA may encompass the mere detection of the DNA in the sample, however, analyzing may mean determining the structure or other properties of the nucleic acid. This rejection may be easily overcome by amending the preamble to recite analyzing or alternatively amending the final process step to characterizing such that they are the same.

Conclusion

16. **No Claims are allowable over the prior art.**

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

A) Burgoyne (US Pat. 5,756,126, May 1998) teaches a dry solid medium for storage and analysis of genetic material. Burgoyne teaches that a chelating agent, a anionic detergent or surfactant may be dried upon the solid support (col. 8-9). Burgoyne teaches that the components for subsequent analysis are preferably included on the dry solid medium before subsequent treatment of the genetic material (GM)(col. 14, lines 27-30). Further, various permutations for inclusion of the components are possible. Burgoyne teaches analyzing the nucleic acids following lysis.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

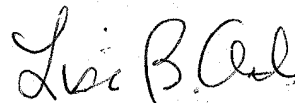
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Enewold Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Thursday from 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 308- 4242.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Enewold Goldberg
June 28, 2001


LISA B. ARTHUR
PRIMARY EXAMINER
GROUP 1800-1600